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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,129	06/24/2003	David J. Schuessler	33915-03420	9875

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ALLERGAN, INC.
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EXAMINER

MIGGINS, MICHAEL C

ART UNIT	PAPER NUMBER
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1772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/603,129

Applicant(s)

SCHUESSLER, DAVID J.

Examiner

Michael C. Miggins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,32-36 and 39-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,32-36 and 39-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/3/06 has been entered.

REJECTIONS WITHDRAWN

2. All of the 102 and 103 rejections set forth in the non-final rejection of 11/3/05, pages 2-5, paragraphs 3-8.

REJECTIONS REPEATED

3. There are no rejections repeated.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 32-36, 39-42, 45-49 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al. (US 4960425).

Claim 32 contains the method limitation "rotationally molded" which is a method limitation in a product and has been given little patentable weight since the method limitation does not structurally further limit the product (MPEP 2113). Claims 39-42 contain method limitations as to how the silicone is cured (acetoxo-cured, platinum catalyzed, tin catalyzed) which have been given little patentable weight because the limitations do structurally further limit the product claim (MPEP 2113).

Claims 32-34 and 46 recite limitations concerning the liner for the apparatus used to manufacture the recited product, a medical article. Apparatus limitations in a product claim are not germane to the patentability of the product in a product claim. In the instant claims the liner of the apparatus merely imparts a textured surface to the medical device. A textured surface is disclosed by the prior art as discussed below and thus the liner of the apparatus is not germane to the patentability of the recited product, a medical device. As such the prior art need not disclose the recited mold liner to read on the instant claims as written.

Yan discloses a medical article, breast implant (abstract), comprising a shell defining an interior cavity, said shell being formed of at least one layer of a non-olefin polymer material, wherein said shell is textured (column 8, lines 5-33), seamless (column 7, lines 5-15), filled with a silicone gel, a saline solution, or a foam (column 2, lines 32-47), wherein the polymer material is silicone, polyurethane, or elastomer (column 8, lines 5-33), an external molded surface which exhibits the surface features

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imparted to it by a mold liner (column 7, lines 53-63), wherein said shell has a thickness of from about 0.005 inches to about 0.06 inches (column 5, lines 52-68 and column 7, lines 6-25).

6. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by either Prah (US 4426742) or Pangman (US 3366975).

Claim 26 contains the method limitation "rotationally molded" which is a method limitation in a product and has been given little patentable weight since the method limitation does not structurally further limit the product (MPEP 2113).

Prah discloses a shell of a breast prosthesis which is patchless (column 6, lines 25-65) since the opening is simply closed and no patch is used and wherein the shell is formed of at least one layer of a non-olefin polymer material (column 4, lines 22-32 and fig. 3).

Pangman discloses a shell of a breast prosthesis (column 3, lines 52-63) which is patchless (column 5, lines 24-64) since the perforations are left undisturbed and wherein the shell is formed of at least one layer of a non-olefin polymer material (column 4, lines 30-61).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425) in view of Pinchuk et al. (US 5376117).

Yan fails to disclose wherein the polymer is solvent based.

Pinchuk discloses a shell for a breast prosthesis which is solvent based (column 3, line 34 through column 4, line 39 and column 8, lines 5-62) for the purpose of providing improved strength and biocompatibility (column 4, lines 40-45).

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided a polymer which is solvent based in the breast prosthesis of Yan in order to provide improved strength and biocompatibility as taught or suggested by Pinchuk.

9. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425) in view of Gould et al. (US 5120816).

Yan fails to disclose where the polymer material emits gaseous by-products during curing.

Gould discloses mammary implants where the polymer material emits gaseous by-products during curing (column 5, lines 51-68 and column 10, lines 30-46) for the purpose of providing improved strength (column 6, lines 22-30).

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided a polymer material which emits

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gaseous by-products during curing in the breast prosthesis of Yan in order to provide improved strength as taught or suggested by Gould.

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425) in view of either PrahI (US 4426742) or Pangman (US 3366975).

Yan fails to disclose wherein the shell of the prosthesis is patchless.

PrahI discloses a shell of a breast prosthesis which is patchless (column 6, lines 25-65) since the opening is simply closed and no patch is used for the purpose of providing a stronger prosthesis less likely leak and/or ease of construction.

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided wherein the prosthesis is patchless in the breast prosthesis of Yan in order to provide a stronger prosthesis less likely leak and/or ease of construction as taught or suggested by PrahI.

Pangman discloses a shell of a breast prosthesis (column 3, lines 52-63) which is patchless (column 5, lines 24-64) since the perforations are left undisturbed in order to provide improved adhesion to body tissue (column 2, lines 50-56).

Therefore it would have been obvious to have provided wherein the prosthesis is patchless in the breast prosthesis of Yan in order to provide improved adhesion to body tissue as taught or suggested by Pangman.

ANSWERS TO APPLICANT'S ARGUMENTS

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9. Applicant's arguments of 10/17/06 have been carefully considered but are deemed unpersuasive.

Applicant has argued that Yan does not disclose a removable liner. However, the liner is part of the apparatus used to manufacture the medical device and the recited claims are product claims not apparatus claims. Apparatus limitations in a product claim are not germane to the patentability of the product in a product claim. In the instant claims the liner of the apparatus merely imparts a textured surface to the medical device. A textured surface is disclosed by the prior art as discussed above and thus the liner of the apparatus is not germane to the patentability of the recited product, a medical device. As such the prior art need not disclose the recited mold liner to read on the instant claims as written.

Applicant argues that Prah1 actually discloses a patch since the glue-on adapter (50 from Fig. 1) functions as a patch. However, the glue-on adapter does not function as a patch at all. The glue on adapter allows rotation of the prosthesis in order to provide correct fitting position the glue on adapter does not function as a patch.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael C. Miggins
Primary Examiner
Art Unit 1772



MCM
October 5, 2006